

Appl. No. : **10/791,075**
Filed : **March 1, 2004**

REMARKS

The foregoing amendments and the following comments are responsive to the objections and rejections set forth by the Examiner in the March 19, 2007 Office Action.

Claims 1-16 and 24-30 are pending in this application. The Examiner rejected Claims 1-16 and 24-30. In particular, the Examiner rejected Claims 1-7, 10, 12-14, 16, and 24-30 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Publication No. 2002/0110485 A1 ("the Stringer et al. publication"). The Examiner rejected Claim 8 under 35 U.S.C. § 103(a) as being unpatentable over the Stringer et al. publication in view of U.S. Patent No. 6,264,601 ("the Jassawalla et al. patent"). The Examiner further rejected Claims 9 and 15 under 35 U.S.C. § 103(a) as being unpatentable over the Stringer et al. publication in view of U.S. Patent No. 6,769,871 ("the Yamazaki patent"). The Examiner further rejected Claim 11 under 35 U.S.C. § 103(a) as being unpatentable over the Stringer et al. publication in view of U.S. Patent No. 5,823,987 ("the Elgas et al. patent"). In view of the following discussion, reconsideration of the application is respectfully requested.

REJECTION OF CLAIMS 1-7, 10, 12-14, 16, and 24-30 UNDER 35 U.S.C. § 102(b)

The Examiner rejected Claims 1-7, 10, 12-14, 16, and 24-30 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Publication No. 2002/0110485 A1 ("the Stringer et al. publication").

Claim 1

The Stringer et al. patent publication appears to disclose an integrated blood processing assembly 31 with a single housing 40, further comprising several chambers 55, 50, 47, 48, 54, etc., a blood pump impeller 75, an integral filter 59, a gas removal system 50, 46, and an oxygenator system 53, 70. The Stringer et al. patent publication appears to disclose a blood pump chamber 55 wherein the impeller 75 is physically located in a chamber 55, which is an entity separate from the gas collection plenum 50. The gas removal chamber 50 and the blood pump chamber 55 are contained within an integral housing 40 but are separate components. The impeller 75 of the Stringer et al. patent publication is strictly a blood pump and is not configured to rotate blood circumferentially within the gas collection plenum other than due to passive effects

caused by the tangential blood inlet line 41. As such, the impeller 75 is not claimed to, and cannot physically impart rotational motion to the blood in the gas removal system because it is separated from the gas collection plenum by the long connection tube 15 1 (Figure 8). Thus the impeller 75 is not able to impart centrifugal effects to remove the air from the blood any more than a separate blood pump would do with a blood filter having a tangential inlet line. This is evidenced since the impeller 75 is operably located downstream of the gas removal chamber 50 and thus any rotational energy imparted by the impeller would not be imparted upstream in the gas removal chamber 50, especially since a particulate filter, which would substantially damp out any rotational motion, separates the two chambers.

In contrast, in an embodiment of the invention, air is removed from blood within a chamber defined by a housing, the system comprising an impeller located within the housing, driven by a motor, that actively spins the blood circumferentially about an axis to generate centrifugal forces on the blood to force the buoyant air to migrate radially toward the center of the chamber within the housing where it is removed by a gas vent. In an embodiment of the invention, the impeller is able to rotate the blood at a much higher rotational rate than could a passive tangential inlet line where the blood flow is generated by the impeller of a blood pump. The impeller of the invention is not a blood pump and does not serve to pump blood into or out of the filter chamber. The pumping action of the invention needs to be generated by a separate blood pump, such as that of Stringer et al.

In summary, there appears to be no suggestion or disclosure of a single chamber comprising an impeller within the chamber that spins the blood to force gas to migrate to the center by centrifugal effects, for removal, as taught by Stringer et al. The Stringer et al. patent publication appears not to disclose a centrifugal type gas removal apparatus wherein the blood is spun by a non-pumping impeller to generate the centrifugal forces by a motor driven impeller within the same chamber. There appears to be no motivation or suggestion to use the impeller device as a gas removal apparatus since the impeller is not located within the same chamber where the air is removed from the blood.

Appl. No. : **10/791,075**
Filed : **March 1, 2004**

Because the reference cited by the Examiner does not appear to disclose, teach or suggest an apparatus adapted for removing gas bubbles from blood comprising an axially elongate shell defining a chamber, an impeller disposed within the chamber, wherein the impeller does not substantially impart any force either to drive inflow of blood to, or outflow of blood from, the chamber, a motor operably connected to the impeller, a gas vent in fluid communication with the central axis of the shell, a blood inlet port; and, a blood outlet port located at the radial periphery of said shell, wherein the impeller is configured to rotate a volume of blood within the chamber about the central axis of the shell thus forcing air bubbles within the volume of blood to migrate radially inward in response to centrifugal forces imparted on the volume of blood by the rotation of said blood, Applicants assert that Claim 1 is not anticipated by Stringer et al. Applicants therefore respectfully submit that Claim 1 is patentably distinguished over the cited reference and Applicants respectfully request allowance of Claim 1.

Claims 2-7, 10, 12-14, and 16

Claims 2-7, 10, 12-14, and 16, which depend from Claim 1, are believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

Claim 24

The Stringer et al. patent publication appears to disclose a blood handling system with a single housing comprising several chambers, a blood pump system, an integral filter, a gas removal system, and an oxygenator system. The Stringer et al. patent publication appears to disclose a blood pump wherein the impeller is physically located in a chamber separate from the gas removal system, although the two separate chambers are contained within an integral housing. The impeller of the Stringer et al. patent publication is a blood pump and does not appear to impart rotational motion to the blood in the gas removal system and thus does not appear to be able to actively impart centrifugal effects to remove the air from the blood.

In contrast, in an embodiment of the invention, air is removed from blood within a housing comprising an impeller, driven by a motor, that actively spins the blood

Appl. No. : 10/791,075
Filed : March 1, 2004

circumferentially about an axis to generate centrifugal forces on the blood to force the buoyant air to migrate radially toward the center of the housing where it is removed by a gas vent. In an embodiment of the invention, the impeller serves to rotate the blood but does not generate any blood pumping action.

In summary, there appears to be no suggestion or disclosure of a single chamber comprising an impeller that spins the blood to force gas to migrate to the center by centrifugal effects, for removal, as taught by Stringer et al. The Stringer et al. patent publication appears not to disclose a centrifugal type gas removal apparatus wherein the blood is spun to generate the centrifugal forces by a motor driven impeller residing within the gas removal chamber. There appears to be no motivation or suggestion to use the device as a gas removal apparatus since the impeller is not located within the same chamber where the air is removed from the blood.

Because the reference cited by the Examiner does not appear to disclose, teach or suggest an apparatus adapted for removing gas bubbles from blood comprising an axially elongate shell defining a chamber, an impeller disposed within the chamber, wherein the impeller rotates about an axis concentric with the axis of the shell, further wherein the impeller is configured to rotate a volume of blood substantially filling the chamber about the axis of the shell, further wherein the impeller does not substantially impart any force to drive either inflow of blood to, or outflow of blood from, the chamber, a motor operably connected to the impeller to cause the impeller to rotate about its axis, a gas vent in fluid communication with the central axis of the shell, wherein gas collected along the central axis of the shell is removed from said shell through the gas vent, a blood inlet port operable to fill the chamber with blood, and a blood outlet port located at the radial periphery of said shell, wherein said blood outlet port is operable to drain blood from the chamber, wherein the blood inlet port receives blood that has been drained from a patient's body and the blood outlet port delivers blood back to a patient, wherein the blood delivered back to the patient has had air bubbles removed primarily by centrifugal forces generated on the air bubbles by the rotating blood within the apparatus, Applicants assert that Claim 24 is not anticipated by Stringer et al. Applicants therefore respectfully submit that Claim 24 is patentably distinguished over the cited reference and Applicants respectfully request allowance of Claim 24.

Claims 25-29

Claims 25-29, which depend from Claim 24, are believed to be patentable for the same reasons articulated above with respect to Claim 24, and because of the additional features recited therein.

Claim 30

The Stringer et al. patent publication appears to disclose a blood handling system with a single housing comprising several chambers, a blood pump, an integral filter, a gas removal system, and an oxygenator system. The Stringer et al. patent publication appears to disclose a blood pump wherein the impeller is physically located in a chamber separate from the gas removal system, although the two chambers are contained within an integral housing. The impeller of the Stringer et al. patent publication does not appear to impart rotational motion to the blood in the gas removal system and thus does not appear to be able to impart centrifugal effects to remove the air from the blood.

In contrast, in an embodiment of the invention, air is removed from blood within a housing comprising an impeller, driven by a motor, that actively spins the blood circumferentially about an axis to generate centrifugal forces on the blood to force the buoyant air to migrate radially toward the center of the housing where it is removed by a gas vent. The impeller of the invention does not substantially force blood either into or out of the chamber in the fashion of a pump.

In summary, there appears to be no suggestion or disclosure of a single chamber comprising an impeller that spins the blood to force gas to migrate to the center by centrifugal effects, for removal, as taught by Stringer et al. The Stringer et al. patent publication appears not to disclose a centrifugal type gas removal apparatus wherein the blood is spun to generate the centrifugal forces by a motor driven impeller. There appears to be no motivation or suggestion to use the device as a gas removal apparatus since the impeller is not located within the same chamber where the air is removed from the blood.

Appl. No. : **10/791,075**
Filed : **March 1, 2004**

Because the Stringer et al. reference cited by the Examiner does not appear to disclose, teach or suggest an apparatus adapted for removing gas bubbles from blood comprising an axially elongate chamber comprising a shell, means for adding blood to the chamber, means for impelling rotation to the blood within the chamber about the axis of the chamber, whereby gas in the blood is released and collected within the chamber near its central axis due to centrifugal effects generated by the rotating blood, wherein the means for impelling rotation to the blood within the chamber does not substantially force blood flow into or out of the chamber, means for venting the gas bubbles collected within the chamber; and means for removing blood from the chamber, whereby at least a portion of the gas bubbles have been removed from the blood, Applicants assert that Claim 30 is not anticipated by Stringer et al. Applicants therefore respectfully submit that Claim 30 is patentably distinguished over the cited reference and Applicants respectfully request allowance of Claim 30.

REJECTION OF CLAIM 8 UNDER 35 U.S.C. § 103(a)

The Examiner rejected Claim 8 under 35 U.S.C. § 103(a) as being unpatentable over Stringer et al. publication in view of U.S. Patent No. 6,264,601 ("the Jassawalla et al. patent").

Claim 8

Claim 8, which depends from Claim 1, is believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

REJECTION OF CLAIMS 9 and 15 UNDER 35 U.S.C. § 103(a)

The Examiner rejected Claims 9 and 15 under 35 U.S.C. § 103(a) as being unpatentable over the Stringer et al. publication in view of U.S. Patent No. 6,769,871 ("the Yamazaki patent").

Appl. No. : **10/791,075**
Filed : **March 1, 2004**

Claims 9 and 15

Claims 9 and 15, which depend from Claim 1, are believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

REJECTION OF CLAIM 11 UNDER 35 U.S.C. § 103(a)

The Examiner rejected Claim 11 under 35 U.S.C. § 103(a) as being unpatentable over the Stringer et al. publication in view of U.S. Patent No. 5,823,987 ("the Elgas et al. patent").

Claim 11

Claim 11, which depends from Claim 1, is believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

CONCLUSION

In view of the forgoing, the present application is believed to be in condition for allowance, and such allowance is respectfully requested. If further issues remain to be resolved, the Examiner is cordially invited to contact the undersigned such that any remaining issues may be promptly resolved.

Respectfully submitted,

Dated: 18 June 2007

By: Jay A Lenker
Jay A. Lenker, Inventor
(949) 494-3645 Home
(949-322-6929 Mobile)